

Remarks

Amendments to the Claims

Entry of the above amendments and reconsideration and withdrawal of the rejection of claims 10-12, 40-43, 46-48 and 50-55 is respectfully requested. Claim 10 has been amended by addition of the term “orally” in two instances and by correcting the spelling of the term “co-administering.” Support for this amendment is in the specification, particularly at page 13, lines 27-30 and page 51 lines 16-23. Claim 46 has been amended by addition of the term “orally” in two instances. Support for this amendment is in the specification, particularly at page 13, lines 27-30 and page 51 lines 16-23. Applicants respectfully submit that no new matter was introduced by these amendments.

35 U.S.C. § 102(e) Rejection of Claims 10-12, 40-41, 47-48 and 50-55

Claims 10-12, 40-41, 47-48 and 50-55 have been rejected under 35 U.S.C. 102(e) as allegedly being unpatentable over Place et al. (U.S. Patent 6,306,841, issued October 23, 2001, hereinafter referred to as “Place”). The Examiner has alleged that Place teaches a composition for treating female sexual dysfunction and that estrogen antagonists such as tamoxifen, raloxifene and centchroman are disclosed. Applicants respectfully request the Examiner reconsider this rejection in view of the amendments to the claims.

Applicants presently claim a method of treating sexual arousal disorder in a female by oral administration of an estrogen agonist/antagonist, and oral co-administration of a cyclic guanosine 3', 5'-monophosphate elevator. Place does not teach or disclose the presently claimed method of treating sexual arousal disorder by oral administration of an estrogen agonist/antagonist, and oral co-administration of a cyclic guanosine 3', 5'-monophosphate elevator and therefore does not anticipate claims 10-12, 40-41, 47-48 and 50-55, as amended.

Place does not supply each of the elements of the presently claimed invention. The method of instant claims 10-12, 40-41, 47-48 and 50-55 requires oral administration of the estrogen agonist/antagonist and cyclic guanosine 3', 5'-monophosphate elevator. Place discloses the local administration of vasodilating agents to the vagina, urethra or vulvar area. The method of Place requires that a vasoactive agent is administered by “vaginal delivery”, “vulvar delivery”, or “urethral

delivery" (see Place at column 4, lines 32-36; column 5, lines 65-67 and column 6, lines 1-19). Place does not disclose any method whatsoever of oral administration of a pharmaceutical composition and makes no mention of oral administration of an estrogen agonist/antagonist, and oral co-administration of a cyclic guanosine 3', 5'-monophosphate elevator to treat sexual arousal disorder as instantly claimed.

Second, Place does not disclose the instantly claimed method employing the combination of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator as in instant claims 10-12, 40-41, 47-48 and 50-55. Place generically discloses numerous possible combinations of vasoactive agents with other classes of agents for administration to the vagina, vulvar area or urethra. However, Place makes no specific disclosure of use of a combination of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator in the methods therein. Particularly, with respect to claims 47-48, Place does not disclose or suggest the method employing the specific combination comprising the compound (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydronaphthalene-2-ol. Since Place does not disclose the elements required in the present method of treating sexual arousal disorder by oral administration of an estrogen agonist/antagonist along with oral co-administration of a cyclic guanosine 3', 5' monophosphate elevator, it thus does not anticipate the instant method of claims 10-12, 40-41, 47-48 and 50-55. For this reason applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. § 102(e) rejection of claims 10-12, 40-41, 47-48 and 50-55, as amended.

35 U.S.C. § 103(a) Rejection of Claims 42, 43 and 46

Claims 42, 43 and 46 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Place. Applicants respectfully request that the Examiner reconsider this rejection in view of the amendment to the claims. Place does not teach or suggest the presently claimed method of treating sexual arousal disorder by oral administration of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator as in instant claims 42-43 and 46.

Place does not supply the elements of the instant claims 41-43, nor does it suggest the presently claimed method. Place is concerned with the local administration of vasodilating agents to the vagina, vulva or urethra as described above. Place does not mention or suggest the particular estrogen agonists/antagonists that are recited in claims 42-43 or 46. One of ordinary skill in the art, in view of Place and employing ordinary creativity and exercising common sense would not arrive at the instant method of claims 42-43 and 46. There is no motivation intrinsic to Place to arrive at the present method of claims 42-43 and 46. Place is concerned only with the local administration of compounds to the vagina, vulva or urethra and never mentions oral administration of an estrogen agonist/antagonist together with a cyclic guanosine 3',5'-monophosphate elevator. Thus, there is no suggestion in Place to use oral administration of an estrogen agonist/antagonist in combination with a cyclic guanosine 3',5'-monophosphate elevator to treat sexual arousal disorder in females. Furthermore, Place does not provide motivation to one of ordinary skill in the art to select certain estrogen agonist/antagonists that are not disclosed in Place and then combine them with a cyclic guanosine 3',5'-monophosphate elevator and then modify the vaginal, vulvar or urethral administration method of Place to arrive at the method of instant claims 42-43 and 46.

Applicants respectfully submit that a person of ordinary skill in the art would not be expected to make the three specific changes to Place required to arrive at the instant invention. In view of this, Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. 103(a) rejection of claims 42-43 and 46 as amended.

Objection to Claim 10

Claim 10 has been objected to because the word "co-administering" was misspelled. Claim 10 has been amended and the objected to misspelling has been corrected. Applicants respectfully request the Examiner to reconsider and withdraw the objection to claim 10, as amended.

Conclusion

Applicants believe that, in view of the amendments and remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 10-12, 40-43, 46-48 and 50-55, as amended, is respectfully requested.

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